



Patient Information Sheet

Tiagabine hydrochloride (marketed as Gabitril)

This is a summary of the most important information about Gabitril. For details, talk to your healthcare professional.

FDA ALERT [02/18/2005]– FDA and the Maker of Gabitril are Discouraging the Use of Gabitril to Treat Conditions Other than Epilepsy.

- **Seizures have occurred in patients taking Gabitril for conditions other than epilepsy**
- **Most of the seizures that have occurred in patients without a history of epilepsy have occurred soon after starting Gabitril, or soon after a dose increase. Some seizures occurred after several months of treatment. Some patients had seizures at a very low dose of Gabitril.**
- **Gabitril is only approved for use with other anti-epilepsy medicines to treat partial seizures in adults and children 12 years and older**
- **If you are taking Gabitril, you should not stop the drug on your own; you should speak to your healthcare professional about this as soon as you can.**

The label for Gabitril has been changed to warn healthcare professionals and patients that these seizures can occur in patients without epilepsy.

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

What is Gabitril?

Gabitril is an anti-epilepsy (seizure) drug. Gabitril is used together with other anti-epilepsy drugs to treat partial seizures in adults and children 12 years and older

Who Should Not Take Gabitril?

- The only use recommended in the labeling for Gabitril is treatment of seizures. (See "What is Gabitril?")

Healthcare professionals are allowed to, and sometimes do, prescribe drugs for uses that are not in the labeling. The maker of Gabitril is strongly discouraging Gabitril's use for any condition except for epilepsy because most of the reported seizures with Gabitril occurred in patients being treated for other conditions. However, if you are taking Gabitril for a condition other than epilepsy, you should not

stop taking it on your own; you should speak to your healthcare professional as soon as you can.

What Are The Risks?

- **Seizures in patients without epilepsy:** See FDA Alert.
- **Withdrawal seizures.** Gabitril can increase seizures if it is stopped suddenly in patients with epilepsy. If you have epilepsy, and your healthcare professional has decided that you should stop taking Gabitril, it should be stopped slowly.
- **Thinking and concentration problems, sleepiness and tiredness.** Do not drive a car or operate dangerous machines until you know how Gabitril affects you.
- **Serious rash.** Gabitril may cause a serious and life-threatening rash.
- **Other side effects** include dizziness, lightheadedness, low energy, nausea, nervousness, irritability, tremors, and stomach pain.
- **Tell your healthcare professional** about any medical conditions you have, especially liver problems. Tell your healthcare professional if you are pregnant, planning to become pregnant, or breast-feeding.

Are There Any Interactions With Drugs or Foods?

- Gabitril may interact with other medicines. Tell your healthcare professional about all medicines, vitamins, and herbal supplements you take, especially other medicines used for epilepsy.

How Do I Take Gabitril?

- Gabitril is taken by mouth, with food, exactly as prescribed by your healthcare professional.

**Gabitril FDA Approved 1997
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